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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,277	05/22/2000	Roger K. Cady	57294-012	1639

7590 06/30/2004

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EXAMINER

KIM, VICKIE Y

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/575,277	Applicant(s) CADY ET AL.	
	Examiner Vickie Kim	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-54 is/are pending in the application.
- 4a) Of the above claim(s) 28-30, 33-42 and 45-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 17-27, 31, 32, 43 and 44 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04-2001</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION***Election acknowledged***

Applicants' election of species, naratriptan as the 5HT₁ agonist and COX-2 inhibitor as the secondary agent is acknowledged. In applicants' previous response, applicants amended the claims 17, 36 and 37(non-elected invention) to include the elected invention. Thus, all the pending claims 17-54 are presented for examination and the claims 17-27, 31-32 and 43-44 have been examined only to the extent that they read on use of the elected species in the claimed method. All remaining claims 28-30, 33-42 and 45-54 not drawn to the elected species are withdrawn from further consideration as being non-elected. The following rejections are made.

Priority

1. This application repeats a substantial portion of prior Application No. 09/185,310, filed 11/03/1998 which also claims benefit of 60/064,879 file 11/06/1997, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Applicant's claim for domestic priority under 35 U.S.C. 119(e) and 120 is acknowledged.

However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims of this application. For instance, the essential claimed subject matter included in the instant

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application(i.e.5HT agonist) was not presented in the priority documents, and thus, the benefit of the domestic priority documents are not validated and the filing date(5/22/00) of the instant application would be the earliest effective filing date of the claimed invention.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claims 17-19, 31-32 and 43-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Plachetka(US6060499 or 6,586,458).

The claims are drawn to a composition and a preemptive prophylaxis migraine method using an antimigraine composition wherein the composition contains 5HT₁ agonist as active ingredient. Optionally, the preemptive prophylaxis method uses the composition comprising 5HT₁ in combination with NSAID such as COX-2 inhibitor.

Plachetka (US'499 or '458 hereafter) teaches a method of treating migraine using a 5HT₁ agonist such as naratriptan(1-100mg, see column 5) in

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combination with NSAID(e.g. COX-2 inhibitor), see abstract, claims and col. 7-col.8. US'458 further teaches that the treatment (Plachetka's) provides an initial migraine relief which reduces or abolishes the symptoms from first onset of the precursor indicia of a migraine headache such as the aura and visual "scotoma", see col.8.

It is noted that the aura is a typical prodromal symptom of migraine as evidenced by applicants' own admission, see instant specification page 1, line 30. As clearly evidenced by the teaching of Plachetka's patents, the preemptive prophylaxis migraine method would have been envisaged by the treatment of US'458 which provides the avoidance of migraine by treating precursor symptoms.

Although the terminology used in application and the patent may not be the same, but the function

Thus, all the critical elements required by the instant claims are taught by the cited reference and the claimed subject matter is not patentably distinct.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 17-27, 31-32 and 43-44 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7 and 11 of U.S. Patent No. 6066092. Although the conflicting claims are not identical, they are not patentably distinct from each other because both patents are related to a preemptive prophylaxis migraine method using anti-migraine medication wherein the method utilizing the cognitive test to measure(determine) cognitive changes occurred prior to onset of migraine headache.

Since 5HT1 agonists(e.g. naratriptan) are conventionally known anti-migraine medication as evidenced by applicant's own admission(see disclosure of the instant application('277) and patent(US'092)), it would have been obvious to substitute anti-migraine medication(US'092) with 5HT1 agonist(e.g. naratriptan) because the anti-migraine effects and safety of said anti-migraine medications are well documented and proven where users can obtain maximum benefits from conventionally known therapeutic drug regimens. It is noted that the cognitive changes are also conventionally known prodromal syndromes, see evidentiary documents at PTO-892. Therefore, the claimed subject matter included US'092 patent are embracing the scope of the instant claims and renders the instant claims obvious and not patentably distinct.

Allowable Subject Matter

4. Claims 20-27 are allowable if double patenting rejection is overcome by submitting terminal disclaimer.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 **VICKIE KIM
PRIMARY EXAMINER**

Vickie Kim
June 25, 2004
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